

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

RALPH SIMON,)	Case No. 4:14-cv-1136 (JAR)
)	
Plaintiff,)	
v.)	
SELECT COMFORT RETAIL CORP.,)	MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF ERNEST P. CHIODO
)	
and)	
SELECT COMFORT CORPORATION,)	
)	
Defendant.)	

BACKGROUND

This is a product liability action brought by Ralph Simon (“Plaintiff”) against Select Comfort Retail Corporation and Select Comfort Corporation (collectively “Select Comfort”). Plaintiff alleges he suffers from a number of illnesses due to exposure to *Cladosporium* mold that allegedly formed in his Sleep Number® bed due to a defective design. Plaintiff contends that due to his “chronic exposure” to mold in his Sleep Number® bed, he has sustained severe and permanent impairments. Plaintiff makes these allegations without any scientific evidence, save the *ipse dixit* of Plaintiff’s medical expert, Dr. Ernest P. Chiodo.

At a hefty flat fee of \$30,000, Plaintiff retained professional expert Dr. Chiodo to opine regarding whether Plaintiff “suffered any injury or illness due to mold exposure in this matter.” (Ex. 10 (Chiodo Rpt.) at 1, 5.)¹ In his initial expert report Dr. Chiodo asserts the following array of opinions:

¹ All exhibits cited in support of Defendants’ motion are attached to the Declaration of Andrew S. Hansen and cited hereafter as “Ex.____.”

1. “Ralph Simon has suffered from disease in the form of allergic rhinitis and chronic sinusitis due to exposure to mold from his contaminated mattress.” (*Id.* at 5.)
2. “[D]ue to his treatment with gentamycin [Plaintiff] has suffered permanent hearing loss.” (*Id.*)
3. “His treatment with gentamycin occurred due to his treatment of symptoms believed to be arising out of an infectious disease but were instead due to his mold exposure due to the contaminated mattress in this matter.” (*Id.*)
4. “The treatment with prednisone caused him to develop cataracts.” (*Id.*)
5. “The treatment with prednisone was due to his symptoms arise [sic] from his exposure to the hidden contamination of his mattress due to mold.” (*Id.*)

In addition to these opinions, at his deposition, Dr. Chiodo asserted he is qualified to testify as a biomedical engineer, physician, industrial hygienist, and occupational medicine doctor. (Ex. 9 (Chiodo Tr.) 55:20–56:8, 63:13–21.) Dr. Chiodo further stated: “I’m intending to opine to all my relevant areas of expertise if called upon to do that.” (*Id.* at 55:20–22.)

Falling well short of the reliability requirement of Rule 702, Dr. Chiodo’s opinions amount to a series of unsubstantiated statements backed by no identifiable scientific methodology. Like many of Plaintiff’s proffered “expert” testimony, Dr. Chiodo’s opinions consist of nothing more than Plaintiff’s baseless allegations being spoken through the mouthpiece of a purported expert. Dr. Chiodo’s opinions are inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Select Comfort respectfully moves the expert testimony of Dr. Chiodo be excluded.

ARGUMENT

I. STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY.

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides that:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The Supreme Court's decision in *Daubert* and its progeny require that the trial court act as a "gatekeeper" to ensure that an expert's testimony is not only relevant, but "rests on reliable foundation." *Wells v. Fedex Ground Package Sys, Inc.*, No. 4:10-CV-2080, 2013 WL 5436608, at *4 (E.D. Mo. Sept. 27, 2013) (Ross, J.) (citing *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012)). "For both elements, relevance and reliability, the district court's focus 'must be solely on principles and methodology, not on the conclusions' of the expert." *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 967 (W.D. Mo. 2000) (quoting *Daubert*, 509 U.S. at 595). "The district court must make a 'preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether the reasoning or methodology can be applied to the facts at issue.'" *Id.* (quoting *Daubert*, 509 U.S. at 592–93). When determining reliability, the Court may consider: (1) whether the expert's theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; and (4) whether the theory has "general acceptance." *Daubert*, 509 U.S. at 593–94. Plaintiff must prove admissibility by a preponderance of the evidence. Fed. R. Evid. 104(a).

II. DR. CHIODO IS NOT QUALIFIED TO TESTIFY REGARDING OPTHAMOLOGY, ALLERGIES, OR DEFECTIVE DESIGN.

Attempting to be a "jack of all trades," Dr. Chiodo offers several expert opinions, crossing several fields of study. "[T]he Eighth Circuit has long held that an expert is only permitted to offer testimony within the bounds of his qualifications, and may not offer opinions

outside of his area of expertise.” *Am. Auto. Ins. Co. v. Omega Flex, Inc.*, 4:11CV00305, 2014 WL 859760, at *3 (E.D. Mo. Mar. 5, 2014), *aff’d*, 783 F.3d 720 (8th Cir. 2015). While Dr. Chiodo boasts a laundry list of degrees, including a law degree and an alphabet after his name, Dr. Chiodo is not board-certified as an allergist or an ophthalmologist, and not otherwise qualified to testify regarding mattress design. (Ex. 9 (Chiodo Tr.) 69:9–22, 70:1–2, 72:7–16, 73:4–6, 141:6–142:8.) *See Jenkins v. Slidella L.L.C.*, No. 05-370, 2008 WL 2649510, at *4 (E.D. La. June 27, 2008), *aff’d*, 318 Fed. App’x 270 (5th Cir. 2009) (unpublished) (recognizing that injuries sustained from alleged allergy to mold lie in the field of allergic medicine).

Dr. Chiodo’s lack of qualifications to testify regarding allergies, either generally or as to Plaintiff, became readily apparent in his expert deposition testimony. While discussing Plaintiff’s allergies, Dr. Chiodo was given the skin test results from Dr. Wedner’s clinic and asked whether he could interpret the results. (Ex. 9 (Chiodo Tr.) 44:8–45:3.) In an uncomfortable display of his lack of qualifications, Dr. Chiodo immediately proceeded to (incorrectly) explain, in detail, the medical significance of numeric notations on the skin test results, which in reality are purely administrative notations. (*Compare* Ex. 22 (Wedner Tr.) 63:2–18, *with* Ex. 9 (Chiodo Tr.) 45:4–47:3.) In other words, he bluffed, and lost.

In his report, Dr. Chiodo did not opine on the alleged design defects at issue in this case. However, in his deposition, Dr. Chiodo claimed that he is “prepared to testify as a biomedical engineer about the design defects.” (Ex. 9 (Chiodo Tr.) 135:4–9.) Not only was Dr. Chiodo not timely offered as an expert on design defects, Dr. Chiodo has no experience designing mattresses and is woefully unqualified to testify on any mattress design issues. *Khoury v. Philips Med. Systems*, 614 F.3d 888, 893 (8th Cir. 2010) (design experts must have “training, education, or experience in the design of [the product at issue]”).

Contrary to Dr. Chiodo's beliefs, he is not given carte blanche to opine on any and all topics, rather, Dr. Chiodo's opinions must be limited to those for which he is actually qualified to testify and that have a factual basis in the Complaint. *See, e.g., Winter v. Novartis Pharm. Corp.*, No. 06-4049, 2012 WL 827305, at *5 (W.D. Mo. Mar. 8, 2012) (granting, in part, defendant's motion to exclude portions of expert testimony for which proffered expert was not a qualified expert).

III. DR. CHIODO'S OPINIONS ARE BASED ON THE UNSUPPORTED ASSUMPTION THAT PLAINTIFF WAS EXPOSED TO MOLD.

Dr. Chiodo's entire report is based on the assumption that Plaintiff was "expos[ed] to mold from his contaminated mattress." (Ex. 10 (Chiodo Rpt.) at 5.)

Plaintiff's purported evidence of mold derives from the report of Patsy Duncan, dated August 1, 2013. (*Id.* at 2.) Contemporaneous with this motion, Defendants have filed a motion to exclude the expert testimony of Duncan because it does not comply with the standards of admissibility of expert opinions established by Federal Rule of Evidence 702 and *Daubert*. Upon the exclusion of Duncan's opinion, Dr. Chiodo has "no valid basis on which to hold [mold] exposure to be a cause of [Plaintiff's] problems," *Junk v. Terminix Intern. Co.*, 628 F.3d 439, 449 (8th Cir. 2010), and his opinions are therefore unreliable.

Dr. Chiodo opines that Plaintiff suffered from allergic rhinitis and chronic sinusitis due to "exposure" to mold from his bed. (Ex. 10 (Chiodo Rpt.) at 5.) "'Critical to a determination of causation is characterizing exposure.'" *Bland v. Verizon Wireless, (VAW) LLLC*, 538 F.3d 893, 898 (8th Cir. 2008) (quoting the Federal Judicial Center, *The Reference Manual on Scientific Evidence* 472 (2d ed. 2000)); *Paige v. Harper*, No.1:06CV111, 2010 WL 145156, at *5 (E.D. Mo. Jan. 8, 2010) (same). "The magnitude or concentration of an exposure should be estimated and the temporal aspects of the exposure should be determined—whether the exposure was

short-term and lasting a few minutes, days, weeks, or months, or was long-term and lasted for years.” *Id.* There are no facts upon which Dr. Chiodo can assume that Plaintiff was exposed to mold and this assumption renders his opinion unreliable. (Ex. 24 (Wedner Rtbl.) ¶¶ 3, 5.) Dr. Chiodo fails to address the completed pathway for exposure, which is necessary to find direct cause when alleging an environmental exposure. (*Id.* ¶ 4.)

Even assuming Ms. Duncan’s report to be reliable and admissible (which it is not), by its own limitations, the report is “limited to representing conditions at the time of sampling.” (Ex. 13 (Duncan Rpt.) at 7; *see* Ex. 15 (Hemming Rpt.) at 6.) Thus, at best, this report supports the proposition that on July 26, 2013, the Plaintiff’s foam from inside his mattress, that had been laid out on the ground, transported, and stored in a plastic bag at Plaintiff’s counsel’s office for almost five months, had evidence of *Cladosporium* mold growth. (Ex. 15 (Hemming Rpt.) at 6.) This was a snapshot in time; there is no evidence of the condition of Plaintiff’s foam on, or before, March 2013. Plaintiff has not offered any expert qualified to opine with a scientific degree of certainty that based on Duncan’s testing, mold existed in Plaintiff’s bed on March 2, 2013 or at any time during his use of the product. In fact, it is scientifically impossible to make this determination based on tape lift sampling, which was the sole method of testing performed by Duncan. (Ex. 16 (Hemming Rtbl.) at 7, ¶ 5.)

Moreover, Dr. Chiodo should not be allowed to rely on the Pastore Report. The expert report of Christopher A. Pastore states that the design of Plaintiff’s bed would have allowed “the spores” to “move up” through the bedding material. (Ex. 20 (Pastore Rpt.) at 9.) Pastore does not, however, opine as to how many “spores” can “move up” through the bedding material, nor is Pastore a bed design expert or microbiologist qualified to proffer such testimony. It is impossible to determine the amount of any purported mold exposure without evidence regarding

how long the purported mold existed on Plaintiff's bed, how many spores *can* move up through the bed each time weight is applied to the bed, how many spores *actually* move up through the bed, and whether other molds were present in Plaintiff's home, independent of any alleged mold in his bed.

Plaintiff has failed to identify any evidence to support the proposition that he was, in fact, "exposed" to any purported mold, much less any supportable evidence regarding the extent or level of his purported exposure. To be relevant, the testimony proposed by an expert must be "sufficiently tied to the facts of the case that will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 589–93. In forming his opinions, Dr. Chiodo did not conduct an investigation nor perform any tests capable of supporting the proposition that Plaintiff was "exposed" to mold and, ultimately, there is no expert testimony to support a finding of exposure.

IV. DR. CHIODO DOES NOT RELIABLY CONDUCT A DIFFERENTIAL DIAGNOSIS.

Dr. Chiodo alleges to have performed a differential diagnosis. (Ex. 9 (Chiodo Tr.) 38:6–39:15.) While a properly-conducted differential diagnosis may be scientifically valid for purposes of a *Daubert* analysis, Dr. Chiodo has failed to faithfully apply the methodology to the facts. "A differential diagnosis begins with an expert's 'ruling in' plausible causes of an injury." *Junk*, 628 F.3d at 449 (citing *Kudabeck v. Kroger Co.*, 338 F.3d 856, 860–61 (8th Cir. 2003)). "Then the expert 'rules out' less likely causes until the most likely cause remains." *See id.* "The final result of a differential diagnosis is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiff's injury." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). "While differential diagnoses are generally admissible, they should be excluded if they are scientifically invalid." *Junk*, 628 F.3d at 449 (citing *Kudabeck*, 338 F.3d at 861).

A. Dr. Chiodo Does Not Demonstrate A Proper Basis To “Rule In” Mold Exposure, Gentamycin, and Prednisone As Causes Of Plaintiff’s Alleged Injuries.

Under a differential diagnosis, to properly “rule in” a suspected cause, it must be actually capable of causing the injury. *Nat'l Bank of Commerce v. Ass'd Milk Producers, Inc.*, 22 F. Supp. 2d 942, 963 (E.D. Ark. 1998), *aff'd sub nom.* 191 F.3d 858 (8th Cir. 1999). That is, the cause must be “scientifically plausible.” *Glastetter*, 252 F.3d at 989. As described above, Dr. Chiodo had insufficient facts to conclude that Plaintiff was in fact exposed to *Cladosporium* mold. As detailed below, Dr. Chiodo has no scientific basis to “rule in” Gentamycin or Prednisone as causes of Plaintiff’s alleged injuries. Therefore, Dr. Chiodo’s methodology was applied unreliably and his opinions must be precluded. *Glastetter*, 252 F.3d at 989 (excluding diagnosis because physicians lacked a proper basis for “ruling in” Paraldol in the first place).

B. Dr. Chiodo Ignores Other Probable Causes In The Record.

It is well settled that, following the *Daubert* decision, the reliability of a medical causation opinion requires the proffered expert rule out other likely causes. *Turner v. Iowa Fire and Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000); *Heller v. Shaw Industr., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999); *Claar v. Burlington N.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994). A failure to consider alternative potential causes renders a differential diagnosis “scientifically invalid.” *Tedder v. Am. Railcar Industr., Inc.*, 739 F.3d 1104, 1109 (8th Cir. 2014); *see, e.g., Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006) (affirming exclusion of a toxicologist on medical causation where the toxicologist did not exclude confounding factors leaving open the possibility of competing causes); *Parmentier v. Novartis Pharmaceuticals Corp.*, No. 1:12-cv-45, 2012 WL 2326047, at *4 (E.D. Mo. June 19, 2012) (excluding expert testimony that “failed to rule out several known causes” because he did not have sufficient information regarding the patient); *Paige*, 2010 WL 145156, at *4 (“Even if [Plaintiff’s experts] were able to

link Plaintiff's alleged exacerbated asthma to pepper spray inhalation, they must also rule out other possible causes.”).

Dr. Chiodo does not properly rule in alternative causes of Defendants' purported ailments. In fact, Dr. Chiodo does not even mention possible alternative causes, let alone provide a reasoning why they were ruled out. For instance, Dr. Chiodo's opinion, on its most basic level, is that Plaintiff's injuries derive from an allergy—that is, an allergic reaction to *Cladosporium* mold. Dr. Chiodo, however, *failed to even administer an allergy test*. Rather, Dr. Chiodo conducted an examination and formed opinions solely based on Plaintiff's exam and the proven false patient history as given to him by Plaintiff. (Ex. 24 (Wedner Rbtl.) at ¶ 5–8, 10; Ex. 1 (Simon Tr.) 37:21–38:20.)

Dr. Chiodo performed an unreliable and insufficient examination of Plaintiff, resulting in unreliable conclusions. According to Dr. Chiodo's report, his H.E.E.N.T (head, ears, eyes, nose, and throat) examination does not indicate Dr. Chiodo examined Plaintiff's nose or throat. (Ex. 10 (Chiodo Rpt.) at 3; Ex. 24 (Wedner Rbtl.) at ¶ 6.) Particularly in light of the fact that Plaintiff's complaints were allergen-based, examinations of the nose and throat were imperative. Furthermore, Dr. Chiodo's investigation and intake of Plaintiff's patient history, which is a critical piece in the differential diagnosis, was insufficient to make a reliable diagnosis. (Ex. 24 (Wedner Rbtl.) at ¶ 7) (“One of the most important parts of any physical examination is the history.”). For example, Dr. Chiodo did not gather an adequate patient family history as it relates to allergies, and Plaintiff did not even provide a truthful disclosure of his own allergies. (*Id.* at ¶ 5.) Plaintiff flatly “denie[d] any allergies.” (Ex. 10 (Chiodo Rpt.) at 3.) Based on actual allergy skin testing, a generally accepted method of determining allergies, Dr. Wedner discovered the following:

Mr. Simon's a highly atopic individual and his medical history is totally consistent with this finding. Mr. Simon is sensitive to trees, grasses and weeds which give him seasonal symptoms. He was also reactive to multiple fungal genera including both indoor and outdoor fungi. Interestingly, he is also sensitive to a group of Basideomycetes (mushrooms, toadstools, smuts and rusts) suggesting that he was sensitized to these species from airborne contamination (usually but not necessarily on a farm) outside of his home environment. He was also skin test positive to cat, mouse and dust mite.

(Ex. 23 (Wedner Rpt.) at 7.) Instead of employing a generally accepted method of testing for allergies, Dr. Chiodo uses self-fulfilling logic, concluding that Plaintiff is allergic to mold on the assumption that his health effects were caused by mold. (Ex. 9 (Chiodo Tr.) 42:13–16 (“[W]e know that he is allergic to mold, because that’s the reason why he had the adverse health consequences that led to this issue.”).) Because Dr. Chiodo’s assumptive analysis is based on a proven false patient history, Plaintiff’s lack of veracity undermines the reliability of Dr. Chiodo’s differential diagnosis altogether. (Ex. 24 (Wedner Rbtl.) at ¶ 7.)

Not only did Dr. Chiodo fail to test or consider other potential allergens, Dr. Chiodo did not “rule out” the numerous other potential sources of exposure to *Cladosporium* mold in the Plaintiff’s environment. Testing of Plaintiff’s most frequented environments—including his home (without the product at issue), his place of worship, and his office—demonstrates that when visiting all of these locations, Plaintiff likely comes into contact with organisms to which he could be sensitized, including *Cladosporium*. (Ex. 16 (Hemming Rbtl.) at 4–5.) Moreover, the median outdoor *Cladosporium spp.* concentration in the United States, in clear weather, is 610 spores per cubic meter. (Ex. 7 (Carlson Rpt.) at 3.) Consistent with neighboring states, spore levels in Missouri are likely even higher than the national average. (Ex. 7 (Carlson Rpt.) at 3–4 (“Illinois and Ohio reported median outdoor *Cladosporium spp.* spore levels of 693 and 838 spores per cubic meter respectively.”).)

Failure to consider alternative causes when making a differential diagnosis results in an unreliable and inadmissible diagnosis. *See Roche v. Lincoln Property Co.*, 278 F. Supp. 2d 744, 750 (excluding expert testimony that “fails to distinguish between harms attributable to the mold exposure and the [Plaintiff’s] allergic reactions to other common allergens, such as *casts, dust mites, weeds, grasses, and trees.*” (emphasis added)); *see also Jenkins*, 2008 WL 2649510, at *4 (“Plaintiffs symptoms could be caused by any number of other exposures and/or conditions [Plaintiffs’ expert] failed to perform a differential diagnosis adequate to explain why exposure to Aspergillus mold at Plaintiffs’ apartment ‘is the most probable cause of the Plaintiff’s complaints.’”); *Flores v. Allstate Texas Lloyd’s Co.*, 229 F. Supp. 2d 697, 702 (S.D. Tex. 2002) (finding testimony inadmissible in part because the medical expert’s testimony was not based on “the results of any testing done to determine whether Plaintiffs [were] allergic to any specific type of mold found in their home”).

C. Dr. Chiodo Exclusively Relies On An Unsupported Temporal Relationship.

Dr. Chiodo’s opinions are further unreliable as they improperly rely on a mere “temporal association” as a substitution for reliable scientific proof of causation. *Nat'l Bank of Commerce*, 22 F. Supp. 2d at 963. Plaintiff’s medical expert diagnosis is based primarily on temporal association. (Ex. 9 (Chiodo Tr.) 42:20–43:3, 51:21–23 (“[H]is symptomatology matches his duration of sleeping on the moldy bed.”) Not only is reliance on temporal association improper, Dr. Chiodo’s employs a temporal association that relies on the unsupported and improvable assumption that in or around 2002, mold formed in Plaintiff’s bed and caused Plaintiff to suffer harm. (*Id.* 51:1–53:19.) Further, Dr. Chiodo unfortunately relies on Plaintiff’s fabricated testimony related to his onset of symptoms.

Since his alleged discovery of mold, Plaintiff has offered three drastically different dates for the onset of his symptoms—two under oath and one in his Complaint. First, in November

2013, Plaintiff offered an unsolicited, signed affidavit that swore his physical symptoms attributed to mold began “in 2006.” (Ex. 32 (Simon Aff.) ¶ 4.) When he filed suit on March 14, 2014 (and again in his Amended Complaint filed on March 20, 2015) he alleged his physical symptoms began in “early 2009.” At some point, Plaintiff must have determined that it was beneficial to his case to alter his timeline to manufacture a more closely-related temporal association of his alleged illness to his ownership of the bed, and during his deposition he testified that his symptoms began in the 2002/2003 timeframe. (Ex. 1 (Simon Tr.) 44:7–14; 78:5–10.) Plaintiff was also obviously trying to distance the onset of symptoms, originally swore to be in 2006, from the fact that he entirely changed his environment in 2006—he moved homes—and belatedly realized that would defeat his temporal relationship theory. (*Id.* 24:4–14.)² This fact completely defeats Dr. Chiodo’s theory of causation, because in support of his opinion Dr. Chiodo testified: “I’m not aware of any other exposure circumstance that matches the temporal sequence of his symptomology other than the bed.”³ (Ex. 9 (Chiodo Tr.) 50:19–51:7.)

V. DR. CHIODO’S OPINIONS DO NOT RELY ON SCIENTIFICALLY ACCEPTED PRINCIPLES THAT ARE REASONABLY RELIABLE.

In his expert report, Dr. Chiodo’s states that: (1) gentamycin caused Plaintiff’s hearing loss; and (2) prednisone caused Plaintiff’s cataracts. (Ex. 10 (Chiodo Rpt.) at 5.) Dr. Chiodo’s

² Not only did Plaintiff move homes, but he immediately undertook several home improvement projects which involved tearing out windows and ripping up old carpet. *Id.* (Ex. 1 s(Simon Tr.) 8:2–6, 9:17–11:19.) Plaintiff also admitted in his deposition that he didn’t see any mold on his bed when he moved it in 2006, which further undercuts a relationship between mold and his symptoms if his symptoms began in 2002/2003. (*Id.* 25:18–26:7.)

³ In a sworn affidavit, Plaintiff originally asserted his symptoms related to mold began in 2006. He then changed his story and alleged that they began in 2009 in his Complaint. Then later still, he testified in his deposition that they began in 2002/2003—which is the date Dr. Chiodo relies on. (Ex. 1(Simon Tr.) 78:5–10; Ex. 9 (Chiodo Tr.) 52:1–53:19.) Plaintiff’s changing story is most likely due to the fact that he entirely changed his environment in 2006—he moved homes—and belatedly realized that would defeat his temporal relationship argument.

opinions are not grounded in generally accepted scientific principles, rather they appear to be based on cursory review of the applicable literature and assume a causal connection based on nothing more than his own conclusory statements. “Nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). The trial court has the duty to ensure that expert testimony is both reliable and relevant. This “gate keeping” function ensures that unreliable and irrelevant information, cloaked in the mantle of expertise and science, does not find its way in front of a jury. *See Daubert*, 509 U.S. at 589; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147.

A. There Has Never Been A Report Of Intranasal Gentamycin Causing Ototoxicity.

Dr. Chiodo’s assumption that “gentamycin [is] well known to cause ototoxicity with permanent hearing loss” is not generally accepted in the scientific community. (Ex. 10 (Chiodo Rpt.) at 5.) The single piece of literature that Dr. Chiodo cites in support of his general causation conclusion specifically states that there has only been an association between the prolonged use of inhaled steroids. (*See* Ex. 21 (Sher Rpt.) at 7.) In reality, there has never been a single report of intranasal Gentamycin causing ototoxicity. (Ex. 24 (Wedner Rbtl.) ¶ 8.)

Moreover, Dr. Chiodo’s report neglects the cornerstone of a toxicology diagnosis—the dose-response relationship. The Eighth Circuit requires a Plaintiff prove the levels of exposure that are hazardous to human beings generally, as well as Plaintiff’s actual level of exposure. *See Wright v. Williamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir. 1996). The levels that are reported in the article cited in Dr. Chiodo’s report could not possibly be achieved by intranasal administration. (*See* Ex. 24 (Wedner Rbtl.) ¶ 8.) Plaintiff’s own treating physician, Dr. Craig, agreed with this assessment. (Ex. 3 (Craig Tr.) 137:21–138:5.) Expert opinions that are not

generally accepted must be excluded. Fed. R. Civ. P. 702. Plaintiff has failed raise a genuine issue of fact that Plaintiff's alleged injuries could not have been caused by intranasal administration of Gentamycin.

B. Episodic Prednisone Therapy Does Not Cause Posterior Subcapsular Cataracts.

Dr. Chiodo bases his causation opinion on the predicate that "prednisone [is] well known to cause cataracts." (Ex. 10 (Chiodo Rpt.) at 5 (*citing Furst C, Smiley WK, Ansell BM. Steroid Cataract Ann. Rehum Dis. 1966 25; 364–68.*)) In addition to the single piece of literature cited, in his deposition, Dr. Chiodo stated that his opinion regarding the effects of steroids is further supported in the "Merck Manual" which merely lists steroids as a risk factor with no further details as to type, dosage, or method of causation. (Ex. 9 (Chiodo Tr.) 74:22–76:20.)

On rebuttal, Defendants submitted the expert report Neal A. Sher, MD, FAAO, FACS. Dr. Sher is a medical doctor who, unlike Dr. Chiodo, is Board Certified by the American Board of Ophthalmology and a Fellow of the American Academy of Ophthalmology and the American College of Surgeons. (Ex. 21 (Sher Rpt.) at 2.) In his practice, Dr. Sher has performed thousands of cataract surgeries and continues to take care of thousands of patients with cataract and related conditions. (*Id.*) Unlike Dr. Chiodo, Dr. Sher has participated in several clinical trials as a co-investigator of various medications, including nasal sprays and inhalers that contain corticosteroids, and the development of cataracts. (*Id.*) In his rebuttal, Dr. Sher explains that Dr. Chiodo's opinion overstates the link between steroids and cataracts, and does not take into account the administration of the steroid nor the Plaintiff's specific type of cataract. (*See Ex. 21 (Sher Rpt.) at 7.*)

Dr. Sher explained that the link between steroids and cataracts almost always relates to a *specific type of cataract*—posterior subcapsular cataract. (*Id.*) Plaintiff does not have this type of

cataract; rather, he has trace nuclear sclerosis, which is the most common cataract seen in the elderly. (*Id.* at 3–4, 7.) Dr. Sher describes Plaintiff’s cataracts as “visually insignificant . . . typical of an individual who is in his mid fifties at the time of development.” (*See id.* at 7.) “The most likely cause is a combination of factors including age, life style and genetics.” (*Id.*) Citing peer-reviewed medical literature, Dr. Sher further explained that the formation of posterior subcapsular cataracts linked to corticosteroids is “dose related including the type of steroids, method of administration, dosage, and route. Prolonged use of inhaled steroids has been linked to posterior subscapular cataract. Nasal steroid use has not been associated with this type of cataract.” (*Id.* at 7.) This is also supported by the study Dr. Chiodo cited in his report, with cataract formation after prolonged use of heavy doses. Dr. Chiodo made no distinction between the types of cataracts linked to use of corticosteroids, nor does he analyze dose or method of administration.

Finally, Dr. Chiodo’s diagnosis is also unreliable because it is based on conclusions unsupported by the facts. Dr. Chiodo’s conclusion that Mr. Simon had a rapid onset of bilateral cataracts is not supported by Plaintiff’s medical records. (Ex. 10 (Chiodo Rpt.) at 2–3; Ex. 21 (Sher Rpt.) at 7.) Rather, the cataracts were first noted in 2011 and have not progressed or caused any visual changes. (Ex. 21 (Sher Rpt.) at 7.)

CONCLUSION

Based on the foregoing, Defendants respectfully request the Court exclude the expert reports and testimony of Plaintiff’s expert, Ernest P. Chiodo.

Date: August 28, 2015.

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